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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,554

10/24/2003

Yasuyuki Kawashima

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1129

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

02/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,554	Applicant(s) KAWASHIMA ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-46 is/are pending in the application.
- 4a) Of the above claim(s) 29-32, 36-38 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28, 33-35, 39-44 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/24/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/13/2004, 10/24/2003 and 10/05/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed 12/01/2008 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

3. The drawings remain objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Although, as was pointed out by the Applicant, Figure 16 does show PMT 124 and diode 125 as parts of the flow cell detector, the drawings, as was previously noted, do not clearly show essential components together with their structural and / or operative inter-relationships, as is instantly claimed (that is, the detection unit, the fluid suppliers, the sample preparation unit, the pipette washing unit, and the pipette are not shown as being structurally and / or operatively connected to and / or through the controller such as to provide for the recited functionality).

Specification

4. The previous objection to the specification has been withdrawn, in light of the clarifications provided by the Applicant in the Remarks of 12/01/2008.

Claim Rejections - 35 USC § 112

5. Claims 27-28 and 41-42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Examiner maintains that the specification does not provide sufficient support for the controller configured to control the pipette washing unit and the washing solution supplier such that the “pipette is washed with the washing solution when the analysis result is less than a predetermined value, and the pipette is washed with the acidic solution when the analysis result is equal to or greater than the predetermined value”; or for the controller configured to control the pipette washing unit and the washing solution supplier such that the “pipette is washed with the acidic solution after having been washed with the washing solution when the analysis result is equal to or greater than the predetermined value”, as is currently recited. Contrary to the Applicant’s assertion that the limitations in question are supported by the original disclosure on pages 33- 35, the latter only describe the first pipette 28 being washed inside (when the measured cell count exceeds a certain level) with the acidic dilution solution and consequently being washed from outside with the sheath fluid, which may be slightly alkaline (pH 7.8). Thus, although the original disclosure supports washing the pipette with an acidic solution when the analysis result is equal or greater than a predetermined

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value, it does not support washing the pipette with a solution of lower acidity when the analysis result is less than the predetermined value; nor does it support the “pipette being washed with the acidic solution after having been washed with the washing solution when the analysis result is equal to or greater than the predetermined value , as is currently claimed.

6. Claims 26-28, 33-35, 39-44 and 46 remain rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As was pointed out previously, with respect to claims 26, 35, 40 and 46 reciting a controller “for calculating an analysis result from the detection signal obtained by the detection unit”, it is unclear whether or not this recitation means that the controller must be connected to the detection unit (see also claims 28 and 41-42, with respect to the controller configured to control the pipette washing unit and the washing solution supplier). It is also unclear how the ‘measured sample’ can be prepared without means for measuring diluting liquids. Thus, the claims are incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The same considerations apply to claims 27 and 41-42, with respect to a threshold setting and judging means (which would be necessary to provide for the functionality recited in claims 27 and 41-42).

Regarding claim 35, it remains unclear what structural features would configure the analyzer for being specifically a bacteria analyzer (see also claim 40, with respect to urine analysis).

In claim 44, it is unclear, as was noted earlier, whether or not the controller must be connected to the sheath fluid supplier.

Claim Rejections - 35 USC § 102

7. Claims 26-28, 33-35, 39-44 and 46 are rejected under 35 U.S.C. 102(b) as anticipated by Chupp et al. (US 5631165).

With respect to claims 26, 35, 40 and 46, Chupp discloses an automated analyzer for “distinguishing and differentiating cells in a sample”. The device comprises, as shown in Figures 3- 5, a sample processing area 110 [‘sample preparation unit’], aspiration probe 156 [‘pipette’] and “probe wash and dry unit” 144. The system also includes “a dilution syringe coupled to the tubing network 182”, flow cells / impedance transducers 170, 174, 178 [‘detection units’], panel 114 [holder] accommodating cups 134, 140, 142 for holding reagent and wash solutions / buffers [‘solution containers’], and a controller (see Col.7, lines 20-30). The buffer solutions can be sulfonic acid buffer, citrate buffer, or acetate buffer [‘acidic solutions’] –see Col. 13, lines 18-25.

In reference to claims 33-32 and 39, the Office maintains that the acidic solution and the sample are not positively recited as a part of the claimed invention, and, therefore, they are not accorded patentable weight.

Regarding claims 43-44, Chupp discloses flow cell 170 with a laminar flowing sample stream surrounded by diluent / sheath solution, the sheath solution coming from a supplier - (see (Col.17, lines 4-8).

Double Patenting

8. Claims 26, 35, 40 and 46 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of co-pending Application 11/ 729017. See the appropriate paragraphs of the 05/29/2008 Office Action.

Response to Arguments

9. Applicant's arguments filed 12/01/2008 have been fully considered but they are not persuasive.

Applicant argues that Chupp fails to teach acidic solution, sample preparation unit and pipette washing unit. Examiner disagrees. Chupp does disclose acidic buffers, for example, sulfonic acid buffer, citrate buffer, or acetate buffer (see Col. 13, lines 18-25). Figures 3- 5 also clearly show an analyzer having a sample processing area 110 ['sample preparation unit'], aspiration probe 156 ['pipette'] and 'probe wash and dry unit'144. See the art discussion above.

Conclusion

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10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/

Supervisory Patent Examiner, Art Unit 1797